

MEMORANDUM TO THE NATIONAL ORGANIC STANDARDS BOARD

June 23, 2023

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SUBJECT: Work Agenda Request: Inert Ingredients in Pesticide Products

The National Organic Program (NOP) requests that the National Organic Standards Board (NOSB or Board) continue to work on, and facilitate public discussion about, the topic of inert ingredients in organic production. Inert ingredients are ingredients other than the active pesticide ingredients in a pesticide product. These ingredients can enhance the shelf-life, ease-of-use, and/or efficiency of the pesticide product. Currently, the U.S. Department of Agriculture (USDA) organic regulations allow substances on the U.S. Environmental Protection Agency (EPA) List 3 and List 4 as inert ingredients in pesticide products. However, the EPA no longer supports these lists, and it has not updated them since 2004.

Background

In February 1999, the NOSB recommended that inert ingredients appearing on:

- EPA List 1 and List 2 be prohibited;
- EPA List 3 be prohibited unless specifically approved by the NOSB; and
- EPA List 4 should generally be allowed, unless explicitly recommended for prohibition.

AMS agreed with the NOSB's recommendation and added EPA List 4 to the National List in its December 21, 2000 final rule ([65 FR 80547](#)). This allowed any synthetic substance on EPA List 4 in pesticides containing allowed active ingredients used in organic crop and livestock production. Subsequently, in October 2003, AMS amended the National List to allow EPA List 3 inert ingredients in passive pheromone dispensers for crop production ([68 FR 61987](#)).

These allowances limited disruption to the organic industry because EPA Lists 3 and 4 included most inert ingredients that certifying agents allowed prior to the implementation of the USDA organic regulations. Relying on EPA List 3 and List 4 also reduced the administrative burden on the NOSB and AMS, as the effort to evaluate each allowed synthetic inert substance on the National List would have likely exceeded available resources.

The EPA moved away from the categorical list system, including Lists 3 and 4, while AMS developed regulations to establish the NOP and the USDA organic requirements ([7 CFR part 205](#)). The passage of the Food Quality Protection Act of 1996 ([7 U.S.C. 136 et seq.](#)) required the EPA to develop tolerances (or tolerance exemptions) for inert ingredients used in food-contact

products. These tolerances, which are the maximum amount of a pesticide allowed to remain in or on a food, are codified in EPA regulations at [40 CFR part 180](#). As a result, new and existing inert ingredients are approved for use through EPA's rulemaking process, rather than the previous EPA Lists update.

In response to EPA no longer updating these lists, the NOSB passed an April 2010 recommendation to replace references to EPA List 3 and List 4. This recommendation proposed a system where the NOSB would determine whether each inert ingredient on EPA List 3 and List 4 is either synthetic or natural. Following this determination, the list of the natural inert ingredients would be the preferred inert ingredients for manufacturers when formulating pesticide products for organic production. Under this recommendation, synthetic inert ingredients could only be added to the National List through the petition process. This work was to be conducted through a working group comprised of NOSB members, representatives from the EPA's Design for the Environment/Safer Choice program, and AMS staff. This working group eventually led to the development of a subsequent October 2015 NOSB recommendation.

In October 2015, the NOSB passed another recommendation to replace the National List references to EPA List 3 and List 4. This recommendation suggested replacing these lists with the following three allowances:

- Allow inert ingredients that are permitted in “minimum risk pesticide” products that are exempt from registration as described in the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). (Note: as of February 2016 ([80 FR 80653](#)), this list of inert ingredients is codified at [40 CFR 152.25\(f\)\(2\)](#));
- Allow substances listed on EPA's Safer Choice program's Safer Chemical Ingredients List; and
- Allow inert ingredients exempt from the requirement of a tolerance at [40 CFR 180.1122](#) (only for use in passive pheromone dispensers).

At the end of the NOSB's October 2020 sunset review for EPA List 4, AMS had not yet started rulemaking to address these recommendations. During this meeting, the NOSB also passed a resolution encouraging coordination between the Board and the NOP to replace references to EPA List 4. This resolution requested that AMS work with the NOSB to develop an alternative review process for inerts, work with the NOSB to develop an implementation timeline, and coordinate with the NOSB on progress to develop an alternative to EPA List 4.

Advance Notice of Proposed Rulemaking and Summary of Responses

In response to the NOSB's resolution and previous recommendations, AMS published an Advance Notice of Proposed Rulemaking (ANPR) on September 2, 2022, asking for stakeholder feedback on updated references for inert ingredients in organic production. Because pesticide labels usually do not disclose inert ingredients, the NOP does not know which inert ingredients are currently in use. Therefore, the ANPR asked stakeholders which alternatives (or combination of alternatives) could replace references to EPA List 3 and List 4. These alternatives included referencing various EPA regulations, listing inert ingredients individually in the organic regulations, and keeping EPA List 3 and List 4.

AMS received 386 comments in response to the ANPR. The comments came from a large variety of stakeholders, including certification agencies, inspectors, organic operations, trade & interest groups, and pesticide manufacturers. These commenters overwhelmingly agree that AMS should replace references to EPA List 3 and List 4.

Commenters also largely agreed on two alternatives presented in the ANPR. These alternatives would:

- Allow inert ingredients that EPA allows in minimal risk pesticide products. This alternative references EPA regulations and addresses some of the inert ingredients on EPA List 4.
- Allow inert ingredients EPA allows in passive pheromone dispensers. This alternative also references EPA regulations and addresses all EPA List 3 inert ingredients.

Together, these two alternatives appear to address approximately 70 percent of the various inert ingredients currently used in organic production. Additionally, in 2015 the NOSB supported these alternatives in their recommendation to replace EPA List 3 and List 4, in part, with these two alternatives, mentioned above.

Commenters did not agree on how to address the remaining allowed inert ingredients not covered by these two alternatives. Among these comments, stakeholders identified the following four options to address the remaining EPA List 4 inert ingredients:

- Allow inert ingredients in EPA-registered pesticides without further review. This would be the easiest to implement and an effective way to evaluate products for compliance. This option would require stakeholders to actively engage in EPA rulemaking and may delegate some control of inert ingredients in organic production to the EPA.
- Reference a subset of EPA regulations (e.g., inerts exempt from the requirement of a tolerance) for allowed inert ingredients. This could be combined with an initial list of prohibited inert ingredients. Further prohibitions or allowances may be added through the petition process. This option maintains much of the simplicity of allowing all EPA-registered pesticides while allowing more control. Specifically, it allows stakeholders to submit petitions to prohibit or allow certain inert ingredients as more research is published.
- Develop a single, external list of allowed inert ingredients. The National List would reference this list for allowed inert ingredients. This would function similarly to the current system of referencing EPA List 3 and List 4. This option reduces the sunset burden but is inflexible, like the current reliance on EPA List 3 and List 4. The initial list could be developed from EPA List 3 and List 4, but it is unclear how and by whom this list would be maintained or updated, and how it would fit within the regulatory framework of the National List.
- List allowed inert ingredients individually on the National List in the organic regulations. While the NOSB may be able to initially review these inert ingredients in groups to recommend adding them to the National List, they would need individual sunset reviews every five years. This could nearly double the Board's sunset workload.

The National Organic Program's Request to the National Organic Standards Board

Given the complexity of this issue and all the Board's previous work on this topic, the NOP wants the NOSB to work on finalizing a solution for the references to EPA List 3 and List 4. The Board's consideration is the logical next step in this process, and will help us all find the best path forward through engagement with stakeholders, discussion in subcommittees, solicitation of comments, and discussion at its meetings. At the end of this process, the NOSB should be able to submit a thorough, well-vetted recommendation for rulemaking to the USDA. This recommendation will allow AMS to move to rulemaking and ideally replace the references to EPA List 3 and List 4 before the sunset date of March 15, 2027.

The NOP requests the NOSB to continue work on the topic of inert ingredients in organic production. In doing so, please reference past NOSB work, the information in the ANPR, and comments received. Please continue gathering stakeholder feedback on this topic and provide a recommendation at or before the October 2024 meeting.

In this recommendation, if the Board determines multiple options are viable and consistent with the Organic Foods Production Act, please include those in the recommendation. Having these alternatives will allow AMS to shift to another acceptable option for a final rule without needing to restart the rulemaking process, if needed. Additionally, if affirming part of an earlier NOSB recommendation as part of an option, please include the specific language the Board recommends for the National List.

Thank you in advance for continuing your work on this topic, and we look forward to your discussion and guidance.